

U.S. Patent Application No. 09/488,762
Amendment dated September 26, 2003
Reply to Office Action dated May 27, 2003

REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

The amendment to the claims further define what the applicants regard as the invention. Full support can be found throughout the present application, including the claims as originally filed, for instance, at page 23, lines 11-24, at page 24, line 17 - page 25, line 7. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

Claims 1-10 are pending in the application.

At page 3 of the Office Action, the Examiner rejects claims 1-10 under 35 U.S.C. §102(b) or §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over JP 02-001284, Haffner et al. (U.S. Patent No. 6,096,014), or Wehner et al. (U.S. Patent No. 6,063,981).

The Examiner asserts that each of the cited documents shows medical adhesive materials wherein a base material is formed from a thermoplastic resin having fillers included therein, which fall within the scope of the applicants' claimed silicic acid compound. Thus, the Examiner concludes that the applicants' claimed invention is not novel. The Examiner further states that the stress relaxation ratio property of the claimed invention is considered to be either anticipated by or rendered obvious in view of the compositions described in the references. Thus, the Examiner concludes that since the composition of the claimed invention and the references are identical, it would be reasonable for one of ordinary skill in the art to presume that the prior art possesses properties which either anticipate or render obvious the claimed invention.

For the following reasons, this rejection is respectfully traversed.

U.S. Patent Application No. 09/488,762
Amendment dated September 26, 2003
Reply to Office Action dated May 27, 2003

The claimed invention relates to a medical adhesive tape or sheet including a supporting substrate, and an adhesive layer directly or indirectly laminated thereon, wherein the supporting substrate includes a composition which comprises 100 parts by weight of a thermoplastic resin and 10-200 parts by weight of a silicic acid compound, and wherein the medical adhesive tape or sheet is attachable onto a skin surface.

JP 02-001284 relates to an externally applicable aid which includes porous plastic substrates made of polyolefin resin, characterized by having 100-500 kg/cm of tensile strength, 50% or more of elongation, and 25-100 kg/cm² of 20% modulus. Furthermore, JP 02-001284 relates to an external application aid which is applied on an "injury" which requires aeration and moisture protection. In particular, JP 02-001284 relates to first aid medical sheets, and large scale medical sheet dressings and draping materials, which are formed by coating pressure-sensitive adhesives over porous plastic substrates.

JP 02-001284 is distinct from the claimed invention. There is no teaching or suggestion of a stress relaxation ratio, as for instance, recited in claim 6. There is no evidence why such a property would be inherent in JP 02-001284. This can be seen in the complete English translation of the reference (a copy of which is attached). The material of JP 02-001284 includes a porous plastic substrate and a pressure-sensitive adhesive layer on one side. The substrate requires a porous property for providing sufficient permeability and aeration. Furthermore, the filler described in JP 02-001284 need not be present in the final product. In fact, in one embodiment, the filler may be removed by a solvent after forming a sheet.

U.S. Patent Application No. 09/488,762
Amendment dated September 26, 2003
Reply to Office Action dated May 27, 2003

Furthermore, with respect to the subject matter of claim 5 of the present application, which states that the amorphous or low crystalline polyolefin resin is present in an amount of 30 to 100 percent by weight, this is not taught or suggested in JP 02-001284 or the other cited references. As explained in page 15 of the present application, such an amount of this polymer blend provides the desired stress relaxation properties. Amounts below this level tend to show strong necking to decrease the preferred stress relaxation property. This benefit clearly is not taught or suggested in any of the cited references. Furthermore, the Examiner has not explained in any fashion why the dependent claims, such as claim 5, would be taught or suggested by the cited references. Thus, a *prima facie* case of obviousness has not been established. Furthermore, no anticipation is shown of the subject matter.

Haffner et al. relates to uniaxially oriented microporous breathable films having exceptional toughness transverse to the direction of orientation. The material of Haffner et al. includes a copolymer of ethylene with at least one C₄-C₈ α -olefin monomer. According to Haffner et al., the breathable film is prepared by providing a polymeric resin and adding to the resin at least 40% by weight of a filler having a particle size that contributes to pore formation to form a filled resin. According to Haffner et al. such films have a variety of uses including diapers, training pants, sanitary napkins, incontinence devices, bandages and the like. However, no discussion of stress relaxation properties of the tape in Haffner et al. is made. As illustrated in Example 8 of the present application, the claimed medical adhesive tape or sheet has a significant release relaxation property compared with those of comparative Example 8 which do not include a filler or compared with comparative Example 9 which includes the calcium carbonate of Haffner et al.

U.S. Patent Application No. 09/488,762
Amendment dated September 26, 2003
Reply to Office Action dated May 27, 2003

Wehner et al. relates to the use of an adhesive to prepare a disposable absorbent product, such that the disposable absorbent product exhibits desirable aesthetic properties. More specifically, Wehner et al. relates to an adhesive that is not visible through the outer sheets of the disposable absorbent product. According to Wehner et al., the adhesive is suited for use in disposable absorbent products, such as diapers, adult incontinent products, and bed pads; in catamenial devices, such as sanitary napkins, and tampons; and in outer absorbent products, such as wipes, bibs, wound dressings, and surgical capes or drapes, which are used to absorb a liquid, such as water, saline, synthetic urine and body liquids, such as urine, menses, and blood. Furthermore, Wehner et al., at column 3, lines 24-27 specifically states that the term "adhesive" is intended to mean a substance that is capable of bonding other substances together by surface attachment. Wehner et al. simply does not teach or suggest that the adhesive is attachable to a skin surface. Further, Wehner et al. does not teach or suggest any stress relaxation properties.

Moreover, a combination of JP 02-001284, Haffner et al., and Wehner et al. does not teach or suggest a substrate composition that includes 100 parts by weight of a thermoplastic resin and 10-200 parts by weight of a silicic acid compound. Thus, the Examiner's statement that it would be reasonable for one of ordinary skill in the art to presume that the references include the stress relaxation ratio of the claimed invention is unsupported and is based on hindsight. Furthermore, JP 02-001284 and Haffner et al. are not related to Wehner et al. The adhesive in Wehner et al. is specifically designed for bonding a substance to other substances whereas the adhesive of Haffner et al. and JP 02-001284 can be used in bandages and first aid medical sheets. Thus, one skilled in the art working with adhesives for bandages and first aid

U.S. Patent Application No. 09/488,762
Amendment dated September 26, 2003
Reply to Office Action dated May 27, 2003

medical sheets would not look to Wehner et al. Accordingly, the rejection under 35 U.S.C. §§102(b), 102(e), or in the alternative, 103(a) should be withdrawn.

At page 4 of the Office Action, the Examiner rejects claims 1-8 under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Kobylivker et al. (U.S. Patent No. 6,002,064). The Examiner refers to the Office Action dated December 5, 2002 to support his rejection of claim 1-8. The Examiner further states that the applicants' claims read on a medical sheet. According to the Examiner, a surgical gown is considered to be a medical sheet. The Examiner further states that the fact that the surgical gown is somehow fashioned to fit around a person does not negate the fact that it is a medical sheet. Thus, the Examiner concludes that the claimed invention is anticipated by Kobylivker et al. For the following reasons, this rejection is respectfully traversed.

The claimed invention is a medical adhesive tape or sheet. For such a device to adhere to a patient, it must have a specialized adhesive layer to promote attachment to the body, as is clearly set forth in claim 1. Moreover, for such an adhesive to work properly in health care applications, the adhesive must be pressure sensitive and capable of being removed without damaging the surface of a wound or other sensitive area. As anyone who has ever had a dressing removed from a wound can appreciate, the type of adhesive must be carefully chosen to provide enough adhesion to stick to the body, but the adhesive must also allow removal of the dressing without undue pain to the subject or damage to the skin.

By contrast, Kobylivker et al. shows an article that has a completely different structure and use. While the Examiner characterizes the Kobylivker et al. reference as teaching "medical adhesive articles," this conclusion is not supported in the patent. For instance, Kobylivker et al.,

U.S. Patent Application No. 09/488,762
Amendment dated September 26, 2003
Reply to Office Action dated May 27, 2003

at column 2, lines 46-56 and column 9, lines 55-65, indicates that the film may be useful for the manufacture of gowns, gloves, and other types of medical apparel. However, Kobylyivker et al. does not teach or suggest that it could be used as an adhesive tape or a sheet and be applied directly to the skin, which is a feature of the claimed invention.

Furthermore, Kobylyivker et al. at column 8, describes permanently bonding the film to one or more substrates. This is quite different from the adhesive layer on the substrate of the claimed invention. Particularly, the present application, at pages 23 and 24, states that general classes of adhesives are discussed and it is clear that the adhesives are for purposes of only temporarily adhering the medical adhesive tape or sheet to an object, such as the skin. Also, there is no teaching or suggestion of any stress relaxation property in Kobylyivker et al.

In addition, claim 1 and the claims dependent thereon recite a medical adhesive tape or sheet. Additionally, the language in the claim, at a minimum, is part of the preamble and provides meaning to the claims as further shown in the present specification. As set forth in M.P.E.P. §2111.02 which relates to the weight of a preamble, any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. Clearly, the limitation, "medical adhesive tape or sheet," would not be encompassed by the type of clothing set forth in Kobylyivker et al. The term medical adhesive tape or sheet as set forth in the claims cannot be ignored or rendered generic by the Examiner. Moreover, the claims of the present application specifically recite that the medical adhesive tape or sheet is attachable onto a skin surface. Therefore, Kobylyivker et al. teaches away from the claimed invention. Accordingly, this rejection should be withdrawn.

U.S. Patent Application No. 09/488,762
Amendment dated September 26, 2003
Reply to Office Action dated May 27, 2003

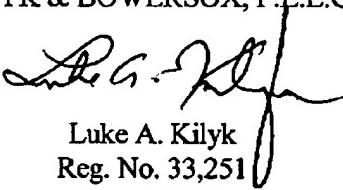
CONCLUSION

In view of the foregoing remarks, the applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

KILYK & BOWERSOX, P.L.L.C.



Luke A. Kilyk
Reg. No. 33,251

Atty. Docket No. 3190-004
KILYK & BOWERSOX, P.L.L.C.
53 A East Lee Street
Warrenton, VA 20186
Tel.: (540) 428-1701
Fax: (540) 428-1720